REMARKS

Claims 1, 4-7, 9-31, 33-37, 39-44, 148 and 149 are pending in the application, and no amendments are being made to the Claims as part of this Reply.

Accompanying the November 16, 2004 Office Action is an Interview Summary record from the Examiner summarizing the substance of a telephone interview on November 3, 2004. The Interview Summary accurately summarizes the substance of the telephone interview. The telephone interview was to discuss generally the status of the application following submission of a response to the prior Office Action of April 5, 2004.

On page 2 of the November 16, 2004 Office Action, Claims 1, 4-7, 9-30, 32-37, 39-44 and 148-149 are listed as pending in the application. This is different than the Office Action Summary, which lists the pending claims as being Claims 1, 4-7, 9-31, 33-37, 39-44, 148 and 149. The listing of pending claims on the Office Action Summary is believed to be correct, and the listing of claims on page 2 of the Office Action is, therefore, believed to be incorrect.

On page 2 of the November 16, 2004 Office Action, Claims 1, 4, 5-7, 9-11, 12, 15, 43-44 and 148-149 are stated to be rejected under 35 U.S.C. § 102(b) as anticipated by Winter et al. (1988) in light of the teaching of Allison (1999). This is the only rejection stated in the Office Action. It is noted, however, that on the Office Action Summary, rejected claims are listed as being Claims 1, 4-7, 9-31, 33-37, 39-44, 148 and 149. Because no specific rejections are stated in the Office Action, however, with respect to pending Claims 13, 14, 16-31, 33-37 and 39-42, it is assumed that those claims are under rejection only as being dependent from a rejected base and/or intervening claim, and would be allowable if written in independent form to include all of the limitations of the base claim and any intervening claims.

With respect to Claims 1, 4, 5-7, 9-11, 12, 15, 43-44 and 148-149 that are rejected under 35 U.S.C. § 102(b) as anticipated by Winter et al. (Infection and Immunity 1988, Vol. 56, No. 11, pp. 2808-2827) in light of the teaching of Allison A (METHODS 1999, Vol. 19, pp. 87-93) and Viegas et al. (U.S. Patent No. 5,300,295), the rejection is traversed, and as noted above a Notice of Appeal is being filed concurrently herewith.

In the November 16, 2004 Office Action, the Examiner states:

> Winter et al. teaches a method for immunizing a mouse model comprising administering each mouse a 100 µl of a vaccine composition comprising 10 µg of antigen, 2.5 µg of reverse temperature copolymer L121 (5%), 10 µg/ adjuvant MDP (10%), 5 µl of sequalane and 95 µl of PBS-Tween . . . [Emphasis Added.]

It is assumed that the parenthesized percentage following each of L121 and MDP refer to the Examiner's estimate of the percentage that component makes up of the administration to each mouse. It is not clear, however, how these estimates percentages have been arrived at. The portion of Winter cited by the Examiner (1st column of page 2810, section (iii)) states:

> Each mouse received 5 µg of antigen, 10 µg of bMDP, 2.5 µg of L-121, 5 µl of squalane, and 95 µl of PBS-Tween.

According to Hawley's Condensed Chemical Dictionary, 12th Edition (1993), squalane has a density at 20°C of 0.805 to 0.812 g/cc. Assuming the squalane of Winter et al. has a density of 0.8 g/cc and the PBS-Tween of Winter et al. has a density of 1 g/cc, then the total weight of the material administered to each mouse according to the cited passage of Winter et al. would be 99,017.5 µg, of which the L-121 polymer would make up only about 0.0025 weight percent, as shown in the following table:

Mouse Model From Winter et al., Page 2810

Component	Component Quantity	Component Weight, μg	Component Weight Percent
antigen	5 μg	5	0.0050
bMDP	10 μg	10	0.0101
L-121	2.5μg	2.5	0.0025
squalane	5μl	4,000*	4.0397
PBS-Tween	95 μl	95,000**	95.9426
Total		99,017.5	99.9999

*calculated, assuming density of 0.8 g/cc, as follows:

(5 μl squalane) x (0.8 g/cc) x (10^{-3} cc/μl) x (10^{6} μg/g) = 4,000 μg squalane

**calculated, assuming density of 1 g/cc, as follows:

(95 μl PBS-Tween) x (1 g/cc) x (10^{-3} cc/μl) x (10^{6} μg/g) = 95,000 μg PBS-Tween

The invention recited in Claim 1 requires, among other things, from 5 weight percent to 33 weight percent of a polyoxyalkylene copolymer and from 60 weight percent to 85 weight percent aqueous liquid. Winter et al. do not disclose such a composition, let alone with the other properties required of Claim 1. For example, the cited passage of Winter et al. includes the L-121 polymer at a concentration of only 0.0025 weight percent, which is over three orders of magnitude smaller than the minimum concentration of polyoxyalkylene block copolymer required by Claim 1.

Although the Examiner does not assert that Allison or Viegas disclose the claimed invention, the Examiner refers to Allison and Viegas et al. in making the rejection, apparently for their teachings in relation to inherent properties that may be present in the formulations disclosed by Winter et al. From a review of Allison and Viegas, neither discloses the claimed invention. In Allison, there is a specific teaching away from the subject matter of pending Claims 7, 148 and 149. In the 1st column of page 89 of Allison, under the heading "Nonionic Block Copolymers", there is a discussion concerning the L-121 polymer in relation to squalane emulsions. In particular Allison states:

> Thus L121 is poorly soluble in water, does not stabilize emulsions and is termed a spreading agent. It adheres to the surface of the oil droplets in aqueous media. [Emphasis added.]

Claims 7, 148 and 149 of the pending application each have a limitation requiring the polyoxyalkylene block copolymer to be dissolved in aqueous liquid at least when the claimed composition is at some temperature. The cited portion of Allison teaches that the L121 polymer in a squalane emulsion adheres to the oil phase (i.e., the squalane) and does not dissolve in the aqueous phase, and this is a teaching away that the squalane-containing vaccine preparation disclosed in the 1st column, page 2810, section (iii) of Winter et al. would include the subject matter of claims 7, 148 and 149.

It seems apparent that the rejected Claims are not anticipated by Winter et al. in light of Allison and Viegas et al., as asserted in the November 16, 2004 Office Action, as discussed herein and as to be further discussed in an Appeal Brief anticipated to be filed within the time required following filing of the Notice of Appeal.

If the Examiner has any questions concerning the amendments or remarks presented herein, the Examiner is respectfully invited to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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